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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Paul Harold Bryson

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07/03/2008

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EXAMINER

YU, GINA C

ART UNIT

PAPER NUMBER

1617

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/628,033	Applicant(s) BRYSON ET AL.	
	Examiner GINA C. YU	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4 and 6-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4 and 6-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 22, 2008 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 16 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 16 recites a composition consisting of a glycol, a 4-30 % of silicone, a quaternium, a polymer viscosity modulator, wherein the composition is suitable for being left on the skin and has a pH of less than 3.0. The presently claimed invention lacks support from original disclosure. All examples contains ingredients other than the

recited components and even applicant's preferred quaternium Incroquat behenyl TMS, which is used through out the examples, contains cetearyl alcohol. The composition of specification, [0014], is not limited to only the presently recited components and contains 2-30 % of silicone and 60-90 % of water. The pH limitation "less than 3.0" also appears to be a new limitation.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 4, 6, 7, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clarke et al. (US 4818523).

Clarke et al. disclose a hair-conditioning composition comprising about 1-2.5 % by weight of dodecyl trimethyl quaternary ammonium compound, about 0.5-1.5 % by weight of a cyclic or linear silicones, and about 1-2 % of a nonionic water soluble cellulose polymer in about 90-94.5 % of an aqueous carrier. See col. 1, bridging par. The reference specifically discloses a composition comprising 0.50 % of a glycol (propylene glycol), 1 % of a silicone (cyclomethicone), 1 % of a quaternium (dodecyl trimethyl ammonium chloride), and 87.5 % of water. See Example 2; col. 9, lines 20 – 52; instant claims 1, 6, and 7. The reference also teaches using 0.1-1% of nonionic cellulose polymer or preferably 0.2-0.5 % of polyvinylpyrrolidone/vinyl acetate, and also indicates that the viscosity of the invention can be varied. See col. 7, lines 19 – 50; col. 9, lines 14 – 20. The prior art meets the limitation, "suitable for a being left on the skin"

because it is obvious that a hair conditioner is safe for topical use and nontoxic to human body, and thus suitable for being left on the skin as well.

The reference teaches that the silicone's function is to improve the wet combing of the hair.

The composition also comprises Germaben II, which is a mixture of parabens. See instant claim 13. The reference teaches making the composition in the range of pH 3-4. See col. 9, lines 20-51. See instant claims 1 and 4.

Regarding the new limitation "free of an alpha-hydroxy acid", although Clarke teaches in col. 8, lines 44 – 48, "[s]uitable acids which may be used when needed are citric acid and the like," the reference still renders the present invention obvious because Example 2 does not indicate any content of the acid in the formulation, and also because the passage in the quotation suggests using the acid only when needed. Furthermore, the mere exclusion of an alpha-hydroxy acid in the present composition is not viewed nonobvious since the reference suggests also using acids other than citric acid, which can be any type of traditional buffering acids other than alpha-hydroxy acids.

The reference teaches that cyclic or linear silicone is used in amount of about 0.5 – 1.5 %, which is within obvious range of the lower limitation of the claimed range. See col. 6, lines 41 –58. Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the

Art Unit: 1617

optimum or workable ranges by routine experimentation.” See In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). In this case, there is no criticality seen in modifying the weight amount of silicone from 1.5 % to 2 %. Given the teaching of the prior art, the skilled artisan would have discovered the optimum weight amount for the silicone by routine experimentations.

Claims 1, 4, 6-9, 11-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Espinoza (US 6709773 B2) in view of Flick (Cosmetic and Toiletry Formulations, 1997, 2nd Ed., Vol. 6).

Espinoza teaches a multi-vesicular emulsion drug delivery composition. The reference teaches using a mixture of behenyltrimonium methosulfate and cetearyl alcohol as an emulsifier. See col. 2, line 61 – col. 3, line 60. See instant claims 9, 11, and 14. A sample sunscreen lotion formulation contains 3 % of Incroquat Behenyl TMS (a blend of behetrimonium methosulfate and cetearyl alcohol), 4 % of glycerin, 66.2 % of water, and avocado oil (a vegetable oil). See instant claims 1, 6, 9, 11-13. Glycols including glycerin, propylene glycol, and butylene glycol are also taught as solvent and moisturizers in col. 5, lines 3-10 and lines 37 – 55, and used in sample formulations. The reference also teaches that moisturizers dimethicone and cyclomethicone are used in 1 % and 5 %, respectively, by weight of a composition. See Self-tanning cream in col. 6, line 62 – col. 7, line 9; col. 5, lines 38 – 56. The specific examples of the reference employ cetyl alcohol and stearyl alcohol which function as viscosity modifier, and the reference further disclose polymeric, viscosity modulators such as hydroxyethylcellulose, xanthan gum, and veegum. See col. 4, line 55 – col. 5, line 2.

Art Unit: 1617

See instant claims 1, 6, and 15. The claimed method of topically applying the topical compositions by rubbing and leaving the composition on the skin is an obvious use of the topical product. See instant claim 15. Thus, Espinoza would have obviously motivated one of ordinary skill in the art at the time of the present invention to modify the teachings of the references and make and use a topical composition comprising a glycol, a silicone, a quaternium, and a polymer viscosity modulator within the weight amount as presently claimed.

Although Espinoza does not specifically teach the pH of the exemplified compositions, the reference indicates that hydroxyethylcellulose is compatible with strontium nitrate and is stable at pH values around 3, which implies the suitable pH range of the prior art compositions. See col. 5, lines 1-2; instant claims 1, 4, and 15.

Regarding the new limitation “free of an alpha-hydroxy acid”, although Espinoza mentions citric acid as a pH adjuster, the reference still renders the present invention obvious because citric acid here is mentioned only as one example of old and well known pH adjusting agents that can be used by a skilled artisan. Espinoza teaches using “other suitable ingredients” well known in cosmetic art, and does not in any way suggest that an alpha-hydroxy acid is a required element to make a prior art composition.

For example, Flick teaches that phosphoric acid and citric acid are interchangeably used to adjust pH of a cosmetic composition. See p. 37, Shower Gel with Mbaruti Oil, Mixing Instruction.

It would have been obvious to the skilled artisan to modify the teachings of Espinoza by adjusting the pH of the compositions with a conventional pH adjusting agent other than citric acid, such as phosphoric acid, as motivated by Flick, because the latter teaches that the art-recognized functional equivalency of the buffering acids. The skilled artisan would have had a reasonable expectation of successfully producing a similar acidic topical composition suitable for cosmetic use without using an alpha hydroxy acid.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Espinoza and Flick as applied to claims 1, 4, 6-9, 13-15 as above, and further in view of Cosmetics Additives (1991).

Espinoza and Flick fail to teach the viscosity modulators of instant claim 10.

Cosmetics Additives teaches that propylene glycol dicaprylate/dicaprate is a luxuriant emollient, moisturizers with excellent lubricity and non-oily skin deposition for creams and lotions. See p. 415; instant claim 10.

It would have been obvious to one of ordinary skill in the art at the time of the present invention to modify the composition of the combined references by adding propylene glycol dicaprylate/dicaprate as motivated by Cosmetics Additives because the latter teaches that it provides luxuriant emolliency and non-oily skin deposition of the cream composition. The skilled artisan would have had a reasonable expectation of successfully producing a stable skin cream composition with enhanced emolliency and skin feel.

Response to Arguments

Applicant's arguments with respect to claims 1, 4, 6-16 have been considered but are moot in view of the new ground(s) of rejection.

Applicant asserts that Clarke fails to teach an amount of each component within, overlapping or even close to the claimed ranges and does not render the present claim obvious. Examiner asserts that the claimed amounts are still within an obvious range of the Clark's disclosure because the prior art teaches the specific function of the cosmetic agents. It would have been obvious for a skilled artisan to modify the teaching and discover an optimal weight range suitable for the desired cosmetic property.

Examiner respectfully disagrees that Clarke somehow suggests that alpha-hydroxy acid is required components for the prior art composition because AHA is not the only buffering acids known in cosmetic art and the disclosed examples do not employ any AHA.

Applicant's argument that the prior art is not suitable for being left on the skin is unpersuasive. There is no evidence that the easily removable hair rinse conditioner will not be left on the skin when applied on the skin. Examiner is of opinion that the term "suitable for being left on the skin" does not provide any more structural limitation than the safety and toxicity of the composition. While applicant's assert that the Flick composition cannot be left on the skin, the argument is unpersuasive because there is no evidence that the composition safe to use on the hair and scalp cannot be left on the skin because due to the presence of a buffering agent in the composition.

Examiner respectfully disagrees with applicant's characterization of Espinoza. The reference does not "generally" disclose a multi-vesicular emulsion drug delivery cream comprising AHA. The reference merely offers an example of an application of the invention wherein the active ingredient may be AHA; the core invention of Espinoza is the multi-vesicular emulsion drug delivery system and not the use of AHA as applicant seems to suggest.

Applicant also argues that the reference fails to render the present invention obvious because it does not teach the claimed weight amount of the thickening agent; the argument is unpersuasive because it is obvious that the amount of a thickening agent controls the viscosity or thickness of the composition. It would have been obvious to a skilled artisan to discover the suitable weight amount of the thickening agent by routine experimentations depending on the desired viscosity of the final product.

With respect to the passage of col. 5, lines 1-2, applicant asserts that there is no sample formulation having hydroxyethylcellulose. However, a lack of disclosure of a specific formulation does not negate the teaching of the statement.

Applicant asserts that Flick is not applicable for the rejection because phosphoric acid is not safe for being left on the skin. Examiner respectfully disagrees; phosphoric acid is a well known buffering agent for cosmetic composition; examiner finds it unpersuasive that a skilled cosmetic artisan would somehow employ a toxic and unsafe agent in a rinse-off composition because it is obvious that the composition will leave residues even after the rinsing off.

Conclusion

Art Unit: 1617

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GINA C. YU whose telephone number is (571)272-8605. The examiner can normally be reached on Monday through Friday, from 8:00AM until 5:30 PM..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gina C. Yu/
Primary Examiner, Art Unit 1617